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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,814	03/04/2004	Guy Gorochov	2121-0180P	3637

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/791,814	GOROCHOV ET AL.
	Examiner	Art Unit
	T. D. Wessendorf	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final for restriction only.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

3-0-0

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 6-10 and 12, drawn to a method for "screening" a phage library for the "design and/or selection of chemokine variants", classified variously in class 435, subclasses 6, 7. 1, DIG 3, 436 and subclass 501.

II. Claims 5 and 11 drawn to a method for "producing" a phage library, classified variously in class 435, subclasses 6, DIG 47.

III. Claims 13-19, drawn to a product described as a compound having antagonist properties to RANTES or to MIP-1a and pharmaceutical composition, classified variously in class 530, subclass 350 and 514, subclass 2+.

IV. Claims 20-21, drawn to a method for preventing and/or inhibiting HIV infection in humans, classified variously in class 514, subclass 2+.

V. Claim 22, drawn to a method for preventing and/or curing inflammatory or malignant diseases, classified variously in class 514, subclass 2+.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II and IV-V drawn to different methods and Group III are drawn to products and compositions (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps.

Groups I-V represent separate and patentably distinct inventions. Groups I, II and IV-V are for the preparation of different products, screening of different characteristics, (such as different binding, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above- identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents. For example, Groups I, II and IV-V represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In the instant case, Group IV or V requires method steps for "treating a patient", which is not required by the method of Groups I and

II. Likewise, Group I requires method steps for "screening a library" which are not required by the method of Groups I and IV-V.

Groups I-II and IV-V represent separate and distinct inventions because Group I-II and IV-V claim a method, whereas Groups III claim products. However, if the applicant argues that Groups (I-II and IV-V) and III are somehow related as process of making and product made, the inventions can be considered to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process. In the instant case, (2) the product as claimed can be made by another materially different process e.g., solid-phase synthesis, split-mix solution phase synthesis, the use of a biochip.

Groups III and Group IV-V are somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.5(h)). In the instant case, (2) the process for using the product as claimed can be practiced with another materially

different product e.g., fusion inhibitors like T-20, 1-1249, integrase inhibitors like diketo acids, thiazolothiazepines; viral capsid formation inhibitors like GPG-NHZ, etc.

These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to patentably distinct species of the claimed invention for Groups I-V. Election is required as follows.

If applicant elects the invention of Group 1, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of chemokine (see claims 5,11)
Applicant must elect, for the purposes of search, a single species of chemokine e.g.,RANTES.

Subgroup 2: Species of GPCR (see claims 5, 11)

Applicant must elect, for the purposes of search, a single species of GPCR e.g., CCRS.

Subgroup 3: Species of phage displayed library (see claims 5,11)

Applicant must elect, for the purposes of search, a single species of phage display library e.g., RANTES-g3P fusion phage.

Subgroup 4: Species of animal cells expressing GPCR (see claims 5,11)

Applicant must elect, for the purposes of search, a single species of animal cells expressing GPCR e.g., human CHO-CCRS cells.

Subgroup 5: Species of assay (see claims 5,11)

Applicant must elect, for the purposes of search, a single species of assay e.g., calcium mobilization, infectivity.

Subgroup 6: Species of activity (see claims 5, 11)

Applicant must elect, for the purposes of search, a single species of activity e.g., anti- HIV activity.

The following are patentably distinct species. Claim 13 is generic.

If applicant elects the invention of Group III, applicant is required to elect from the following:

Subgroup 1: Species of compound (see claims 13,15)

Applicant must elect for the purposes of search, a single species of compound e.g., SEQ ID NO: 2-RANTES(10-68). Please do not elect SEQ ID N0: 24 as this "formula" represents more than one species i.e., the election should result in the election of "one" specifically defined sequence.

Subgroup 2: Species of antagonist properties (see claim 13) Applicant must elect, for the purposes of search, a single species of antagonist properties e.g., RANTES, M1P-IG.

If applicant elects the invention of Group IV or V, applicant is required to elect from the following patentably distinct species. Claim 20 is generic.

Subgroup 1: Species of compound (see claim 20 or 22) Applicant must elect, for the purposes of search, a single species of compound e.g., SEQ ID NO: 2-RANTES(10-68). Please do not elect SEQ ID N0: 24 as this "formula" represents more than one species i.e., the election should result in the election of "one" specifically defined sequence.

Subgroup 2: Species of pharmaceutically acceptable excipient (see claim 20 and 22)

Applicant must elect, for the purposes of search, a single species of pharmaceutically acceptable excipient.

Please Note: Applicants must disclose which claims read on the elected species.

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which

are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must

be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process

claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is(571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

July 6, 2005